US ERA ARCHIVE DOCUMENT

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3 OCT 1983

To:

John A. McCann, Program Coordinator National Laboratory Audit Program Benefits and Use Division (TS-768C)

Subject:

Data Audit Report For Amaze

Request for Examination of Additional Studies

This is in reference to the March 17, 1983, lab audit conducted at the Mobay Stanley Research Farm for the oral LD50 and inhalation LC50 studies on the insecticide Amaze (Oftanol).

Though the oral LD50 study was acceptable, the inhalation LC50 study was reclassified from core to supplementary based on the lab audit. Since this reclassification changes the regulatory status of the study, appropriate notification has been given to the registrant (refer to attached copy of our letter to Mobay).

Because all LC50 inhalation studies conducted by this lab would be inadequate due to the type of exposure system utilized (a modified 55-gallon drum), it is requested that all such studies conducted by Mobay Stanley Research Farm be examined by the NLAP until such time as more adequate inhalation exposure equipment is put into operation. Refer to the attached copy of the August 25, 1983, decision memo to Douglas Campt regarding this request.

William H. Miller Product Manager (16) Insecticide-Rodenticide Branch Registration Division (TS-767)

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